

REMARKS

The Office Action

Claims 1-3, 5, and 7-30 are pending. Claim 30 was withdrawn from consideration and has now been cancelled. Claims 1-3, 5, and 7-29 stand rejected for a lack of enablement. Claims 1, 2, 12-15, 17, 19, 22, 27, and 28 stand rejected for indefiniteness. Claims 1-3, 5, and 7-29 stand further rejected for obviousness-type double patenting over claims 1-16 of Renshaw et al. (U.S. Patent No. 6,103,703; hereafter “Renshaw”). Claims 1-3, 5, 7-14, 16-21, and 27-29 stand rejected for anticipation by Fernandez (*Arzneimittelforschung. Drug Res.* 33:1073-1080 (1983)). Claims 1-3, 5, 7-14, and 16-29 stand rejected for anticipation by Ferrer Internacional, S.A. (International Publication No. WO 01/72288; hereafter “Ferrer”). Claims 17, 18, 20, and 21 stand rejected for anticipation by Wurtman et al. (U.S. Patent Application Publication No. 2003/0114415; hereafter “Wurtman”). Applicants traverse these rejections.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 1-3, 5, and 7-29 stand rejected for lack of enablement. The basis for the rejection is the Office’s belief that “the scope is excessive in view of the disclosed enabling exemplifications.” Applicants disagree.

Applicants maintain their arguments of record presented on November 3, 2006 and incorporate those arguments herein by reference.

Applicants maintain the belief that the Office has applied an incorrect standard for determining whether the present claims meet the enablement requirement. The Office has pointed to M.P.E.P. § 2107 as outlining a different policy for medicinal claims. This section of the M.P.E.P. is entitled “Guidelines for Examination of Applications for Compliance with the **Utility** Requirement,” and the subsection relied on by the Office (§ 2107.03) is entitled “Special Considerations for Asserted Therapeutic or Pharmacological **Utilities**” (emphasis added). Furthermore, the Board decision, *Ex parte Balzarini*, mentioned by the Office, dealt with a utility rejection. Thus, Applicants do not understand why the Office has “rejected out of hand” Applicant’s previous assertions that the present rejection appears to be a utility rejection rather than a scope of enablement rejection. Clarification on this issue is requested.

Applicants also note that it was improper for the Office to ignore arguments merely because they reference M.P.E.P. § 2164. For the record, Applicants note that M.P.E.P. § 2164 is entitled “The Enablement Requirement” and provides a summary of the *Wands* factors and relevant considerations. Moreover, Applicants’ arguments, although referencing that section of the M.P.E.P., are based on the factors for determining enablement laid out by the Federal Circuit in *In re Wands*. Since *In re Wands* is controlling case law on the Office, whether or not cited in M.P.E.P. § 2107, Applicants request consideration of the arguments previously presented and incorporated by reference herein.

Finally, Applicants have reviewed the Pekkanen reference supplied by the Office and disagree with the Office's position that it supports a lack of enablement of the present claims. The Pekkanen reference discusses the relationship between the amount of melatonin produced and incidence of cancer. Nothing in the reference calls into question Applicants' data or extrapolations therefrom in relation to the present claims directed to normalization of the sleep/wake cycle, treating sleep disorders, and increasing cognitive function in a sleep deprived mammal.

Reconsideration of this rejection is requested.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 1, 2, 12-15, 17, 19, 22, 27, and 28 stand rejected for indefiniteness.

The purpose of the definiteness requirement is to ensure that "the scope of the claim is clear to a hypothetical person possessing the ordinary skill in the pertinent art" (M.P.E.P. § 2171). Furthermore, M.P.E.P. § 2173.02 states:

Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A) The content of the particular application disclosure;
- (B) The teachings of the prior art; and
- (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

In addition, "[b]readth of a claim is not to be equated with indefiniteness" (M.P.E.P. § 2173.04). The instant claims are definite under this standard. Each of the bases for rejection will be addressed in turn.

The Office has rejected claims 1, 12, 17, 22, and 27 for reciting “CDP-choline” and not “cytidine diphosphate-choline.” Although the chemical name for CDP already appeared in each of the claims, Applicants have inserted the complete chemical name for CDP-choline in claims 1, 12, 17, and 22, and claim 27 has been cancelled. This basis of the rejection is now moot.

With respect to the rejections of claims 1, 12, 15, 17, and 22 for reciting “compound comprising,” the Office states that the term “comprising” implies “an incomplete disclosure of the identity of the active ingredient,” in response to Applicants’ previous arguments. Applicants incorporate by reference the arguments previously submitted on November 3, 2006. In addition, the definiteness requirement does not require that each chemical entity encompassed by a claim be described in complete molecular detail, but instead only in such detail as required for one skilled in the art to determine the scope of the claims. As classes are routinely used to refer to numerous related compounds both in the scientific and the patent literature, Applicants again assert that one skilled in the art would understand the scope of “a compound comprising cytidine, cytidine monophosphate (CMP)...” as recited in the instant claims. The rejection may be withdrawn.

With respect to the negative limitations recited in claim 12 and 19, Applicants incorporate by reference the arguments previously submitted on November 3, 2006. As stated in the previous reply, the M.P.E.P. § 2173.05 (i) summarizes the current state of the case law that negative limitations are allowed. Applicants are not aware of any support in

the case law for the Office's apparent position that a negative proviso may not include a generic term. For the record, Applicants intend to exclude all physical conditions that could affect the health of the mammal in claim 12 and to exclude all substance abuse disorders from claim 19.

The Office has rejected claim 13 for lack of antecedent basis. Claim 13 is directed to treatment of sleep disorders caused by a substance abuse disorder, which is in turn caused by a drug of abuse as is known to the skilled practitioner. Examples of such disorders include cocaine dependence and alcohol dependence. Moreover, the term "substance abuse disorder" is not evaluated in a vacuum but rather as being consistent with the art usage. For the record, Applicants are not aware of any substance abuse disorders that involve air, water, Fritos®, fish and chips, or triple cheeseburgers. The rejection should be withdrawn.

The Office has rejected claim 14 as being "incomplete because the list of abused substances is not preceded by the term – caused by –,” and requests Applicant "to amend as suggested to insure proper grammatical structure.” Claims 14 and 24 are grammatically correct. Alcohol dependence is a substance abuse disorder rather than causing a substance abuse disorder. That is, alcohol dependence and the other dependencies listed represent a specific type of disorder falling under the generic term substance abuse disorder. The rejection should be withdrawn.

Obviousness-type Double Patenting

Claims 1-3, 5, and 7-29 stand rejected for obviousness-type double patenting over claims 1-16 of Renshaw (U.S. Patent No. 6,103,703) for “substantially overlapping subject matter.” The standard for obviousness-type double patenting is “does any claim in the application define an invention that is merely an obvious variation of an invention claimed in the patent?” (M.P.E.P. § 804).

The claims of Renshaw are directed to methods of preventing or ameliorating a stimulant-induced disorder or methods of preventing or ameliorating stimulant-induced cerebral vasoconstriction sequelae. The instant claims are directed to methods of normalizing the sleep/wake cycle, treating a sleep disorder, or increasing the cognitive function of a sleep-deprived mammal. The instant claims are all related to sleep while the Renshaw claims are silent with respect to sleep. Furthermore, disruption of the sleep/wake cycle, sleep disorders, and decreases in cognitive function may also occur in the absence of a stimulant. Thus, the instant claims are not obvious variations of those of Renshaw.

In reply to these arguments, the Office states that caffeine causes wakefulness and therefore the claims of Renshaw read on claim 24. Again, the standard is not whether there is overlapping subject matter but rather whether the present claims are an obvious variant of the claims of Renshaw. As previously stated, there is nothing in the claims of Renshaw that would indicate that a cytidine-containing compound would treat a sleep disorder as instantly claimed.

Applicants further note that the Office has maintained the rejection of all claims although only presenting an argument with respect to claim 24. For this reasons as well, the rejection should be withdrawn.

Rejections under 35 U.S.C. § 102

Claims 1-3, 5, 7-14, 16-21, and 27-29 stand rejected for anticipation by Fernandez; claims 1-3, 5, 7-14, and 16-29 stand rejected for anticipation by Ferrer; and claims 17, 18, 20, and 21 stand rejected for anticipation by Wurtman.

In order to anticipate a claim, a prior art reference must teach each and every limitation. Applicants traverse the rejection in view of the present amendments and arguments.

Fernandez

The basis for the rejection of all independent claims over Fernandez is that “the administration of CDP-choline to treat insomnia is specifically taught.” All of the independent claims have now been amended to exclude treatment of insomnia. Accordingly, this rejection is now moot.

Wurtman

The basis for the rejection of claims 17, 18, 20, and 21 over Wurtman is that “the treatment of cognitive impairment, before or after physical injury, has been disclosed

many times.” Applicants have not claimed increasing cognitive function under any circumstance. Again, claim 17, directed to increasing cognitive function in a sleep deprived mammal, is not anticipated by Wurtman because the reference fails to teach administration of the compound to mammals **deprived of sleep** in order to increase cognitive function. Without such a teaching, Wurtman cannot anticipate the claims because it does not disclose each and every limitation of claim 17.

The rejection of claim 20 appears to be in error as it depends from claim 12 and not claim 17. Claim 21 has been cancelled. The rejection may be withdrawn.

Ferrer

The basis for the rejection over Ferrer is that “the administration of pharmaceutical compositions including CDP-choline [is] disclosed to effectively treat a variety of symptoms related to alcoholism and withdrawal therefrom including insomnia and disorientation.” Again, all of the independent claims have now been amended to exclude treatment of insomnia. Accordingly, this rejection is now also moot.

CONCLUSION

Applicants submit that claims are in condition for allowance, and such action is respectfully requested. Enclosed is a Petition to extend the period for replying for three months, to and including July 19, 2007, and a check in payment of the required extension

fee. If there are any additional charges or any credits, please apply them to Deposit

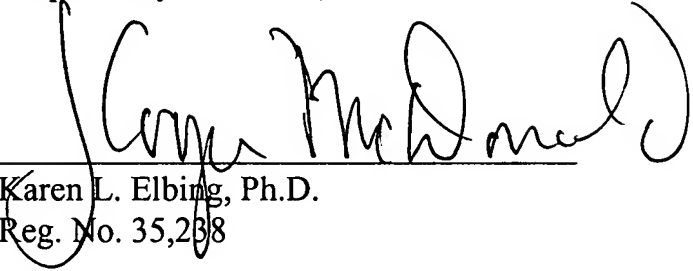
Account No. 03-2095.

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Respectfully submitted,



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